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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,700	10/29/2003	Scott Pownall	029996-0306374	8349

7590 06/27/2006

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/697,700

Applicant(s)

POWNALL ET AL.

Examiner

Maria B. Marvich, PhD

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**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 18-50, 52-59 and 61-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16, 18-50, 52-59 and 61-87 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

This office action is in response to a preliminary amendment filed 4/20/05. Claims 17, 51, 60, 88-126 have been canceled. Claims 1-16, 18-50, 52-59 and 61-87 are pending in this application and subject to restriction.

#### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 2, 4-10, 13-16, 18-28, 54-59, 61-63 and 69-87, drawn to a method comprising expression of a gene product in a cell for increasing glycogen to toxic levels in which synthesis or intracellular accumulation of glycogen is increased in a cell, classified in class 514, subclass 44.
  - II. Claims 3-8, 11-16, 18-28, 54-59, 61-63 and 69-87, drawn to a method comprising expression of a gene product in a cell for increasing glycogen to toxic levels in which metabolism, catabolism, degradation or removal of glycogen is decreased, classified in class 514, subclass 44.
  - III. Claims 30-34, 39-44, 48-51, 53-59, and 61-87, drawn to a method of contacting a cell with an agent for increasing glycogen to toxic levels in which synthesis or intracellular accumulation of glycogen is increased in a cell, classified in class 435, subclass 440.
  - IV. Claims 30-32, 35-37, 39-42, 45-47, 48-51, 53-59 and 61-87 drawn to a method of contacting a cell with an agent for increasing glycogen to toxic levels in which

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metabolism, catabolism, degradation or removal of glycogen is decreased,  
classified in class 435, subclass 440.

The inventions are distinct each from the other because of the following reasons:

Claim 1 links the inventions of Groups I-II. Claims 29 and 38 link the inventions of Groups III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

Inventions of Groups I -IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the instant specification does not disclose that these methods would be used together. The materials and methodology of increasing glycogen

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to toxic levels by expression of a gene product is distinct from the materials and methodology of increasing glycogen to toxic levels by contacting a cell with an agent. Expression of a gene product requires use of vectors and expression constructs and means of expressing the gene product that are not required of methods of contacting a cell with an agent. While methods of contacting a cell with an agent results in direct effect of a cell and does not require that a gene product be expressed. Therefore, the claims are not capable of use and do not overlap in scope. The materials and methods for increasing glycogen in which synthesis or intracellular accumulation of glycogen is increased in a cell are distinct from methods of increasing glycogen to toxic levels in which metabolism, catabolism, degradation or removal of glycogen is decreased. The methods use distinct gene products or agents and use different modes of operation to lead to an increase in synthesis or accumulation versus decrease in catabolism or degradation. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-II and III-IV have a separate status in the art as shown by their different classifications. And a search in the art for methods for increasing glycogen in which synthesis or intracellular accumulation of glycogen is increased in a cell are distinct from a search for art for methods of increasing glycogen to toxic levels in which metabolism, catabolism, degradation or removal of glycogen is decreased. As such, it would be burdensome to search the inventions of Groups I-II and III-IV together.

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This application contains claims directed to the following patentably distinct species: of glycogenic enzymes listed in claims 9, 34 and 44. The species are independent or distinct because the enzymes are structurally and functionally distinct.

Should applicant elect Group I or III, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 33, 43 are generic.

This application contains claims directed to the following patentably distinct species: of glycogenolytic enzymes listed in claims 12, 37 and 47. The species are independent or distinct because the enzymes are structurally and functionally distinct.

Should applicant elect Group II or IV, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 11, 35 and 45 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

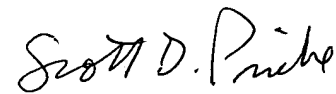
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

  
**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**